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Randomised controlled trial assessing the effects of 6-week telerehabilitation exercise programme on chronic nonspecific neck pain: a study protocol

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Chronic non-specific neck pain is one of the most common

ABSTRACT

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musculoskeletal conditions affecting the work and lifestyle of those suffering from it. Physiotherapy interventions, such as strength training and stretching, have positively influenced neck pain. Patient adherence to home-based exercises is a growing concern that could be easily improved through telerehabilitation exercise programmes. This can also be a cost-effective, time-efficient and patient-suitable service. Therefore, this study aims to establish the effectiveness of telerehabilitation exercise intervention by measuring patient adherence, pain score, disability index, cervical range of motion (CROM) and cervical muscle endurance. This randomised controlled trial will include n=60 participants, aged 18-45 years. in a 6-week home-based exercise programme delivered through telerehabilitation or paper-based instructions. Outcome measures from participants will be obtained at baseline and on completion of 6 weeks. These will include the Visual Analogue Scale for Pain, Neck Disability Index questionnaire. CROM by using the CROM instrument and cervical muscle endurance through the Craniocervical Flexion Test. For baseline differences between groups. an independent samples t-test will be used. Repeated measures analysis of variance will be used for withingroup and between-group analyses at three different time points (0 weeks, 3 weeks, 6 weeks). Trial registration number:NCT06076174.

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BACKGROUND

Chronic non-specific neck pain has become one of the most common musculoskeletal conditions.¹ Most of the people who have this musculoskeletal disorder end up either being unresponsive to any intervention or just not finding any solution to their pain, thus negatively impacting their work and lifestyle.² The rising cost of healthcare, for diagnosis as well as treatment, is one of the main obstacles in getting the right kind of help for those who suffer from neck pain, leading it to become a chronic and persistent part of their lives.³ Numerous studies have identified several risk

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Telerehabilitation interventions have been increasingly popular in recent times.
- ⇒ There is good evidence of the use of telerehabilitation for home-based exercises.
- ⇒ Physical therapy interventions are known to reduce pain intensity and disability for patients with chronic non-specific neck pain.

WHAT THIS STUDY ADDS

- ⇒ To our knowledge, this is the first study to include supervision of exercise sessions through videorecordings in the cloud as part of telerehabilitation.
- ⇒ This study will assess the effects of a home-based exercise programme on exercise adherence, neck pain, disability, cervical range of motion and cervical muscle endurance.
- ⇒ Adherence, as a primary outcome measure, has previously not been evaluated in the context of homebased exercises for chronic non-specific neck pain intervention.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ If the remote exercise programme proves to be beneficial for patient with chronic neck pain, we can recommend it to be used as more cost-effective option.
- \Rightarrow Online programme may prove to be quite useful for people with accessibility issues.
- ⇒ Telerehabilitation will bring easy and convenience with promising results.

factors for neck pain, such as high physical demands of work, improper working environment, stress and anxiety as part of psychosocial factors, vital health-related components such as sleep, a history of chronic low back pain and female gender.⁴

There is ever-growing evidence of the positive influence physical therapy interventions have on pain intensity, level of disability and cervical range of motion (CROM) in these patients. These exercise programmes include

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strength, endurance, stretching and postural training.⁵ Predominantly, isometric exercises and activation of deep cervical flexor muscle have proved to be more effective in relieving chronic neck pain and improving function in addition to postural correction.⁶⁷ Combined strength and endurance training have shown positive results in neck pain and disability, as measured through pain score and Neck Disability Index (NDI).⁸ Likewise, deep neck flexor muscle endurance is a significant outcome measurement, for it is known to be reduced in those afflicted with chronic neck pain. The deep neck flexor endurance test has been established as a reliable part of cervical spine stability assessment.⁹ Patient education is another key factor in determining the effectiveness of patient outcomes following the intervention. In this regard, video-based advice has proved far more successful than simple written instructions.¹⁰

In recent decades, there has been an increased need for cost-effective, time-efficient and patient-suitable exercise programmes.¹¹ Video-based instructions have been recommended for musculoskeletal pain,¹² mainly due to patients' much better adherence to the prescribed exercise programme.¹³ Patients who completed real-time online sessions supervised by their physiotherapist and those who followed prerecorded videos exhibited greater adherence to exercise programmes, lowered pain intensity, enhanced muscle endurance, improved postural alignment and better functionality.¹⁴¹⁵ A duration of 30-45 min for each exercise session has been deemed appropriate and easily attainable. Furthermore, in patients with chronic neck pain, high-frequency exercise interventions are not considered suitable as they have a negative impact on adherence.^{3 16}

Hence, telerehabilitation interventions, which have gained a lot of popularity recently, much of which can be attributed to the global situation brought out by the COVID-19 pandemic,¹⁷ have been opted for in this regard. Telerehabilitation is a mode of healthcare delivery that physiotherapists may use either online (live exercise session on teleconference) or offline (electronic documents, images and prerecorded videos of exercises).¹⁸ This has turned out to be largely beneficial for patients suffering from chronic neck pain, especially those with limited access to healthcare. Other factors that can be conveniently tackled through growing population rehabilitation include time constraints, transportation and high treatment costs.¹² ¹⁴ Several studies have demonstrated the benefits of this mode of healthcare delivery, with particular interest in patient adherence to treatment.^{12 13 15} CareSpace is a digital platform for patient care management, developed by Neave Technologies, tailored to the needs of this study for recording exercises and using in conjunction with the ConnectToMyDoctor application as a means of telerehabilitation.

Chronic neck pain, particularly non-specific, has become a rising healthcare concern. While home-based exercise programmes have proven to reduce neck pain and disability as well as improve functionality in patients, an issue many studies observed was the low adherence of these patients to the prescribed exercises. Consequently, telerehabilitation is deemed an appropriate exercise programme delivery mode to ensure patients consistently follow the prescribed frequency and time of exercise sessions. Therefore, the purpose of this study is to determine if monitoring exercise programmes through telerehabilitation software is as effective as written instructions for patients with chronic non-specific neck pain by way of measuring the pain score, disability index, CROM, cervical muscle endurance and, most importantly, adherence to exercise programme.

METHODOLOGY Study design

A randomised controlled trial (RCT) will be conducted, comparing the effectiveness of two modes of delivery of the same 6-week exercise programme for chronic nonspecific neck pain. The first group will be monitored via the software that records each session so the therapist can review, and the second will have written instructions on paper to follow through on their own. Pretest and post-test measurements will be taken before and after completing the exercise programme at the College of Health Sciences, University of Sharjah. These will include the pain score on VAS Pain (Visual Analogue Scale for Pain),¹⁹ the score on the NDI questionnaire,²⁰ CROM measurement via the CROM instrument¹⁷ and cervical muscle endurance measurement by CCFT (Craniocervical Flexion Test).²¹ The CROM measurements will be carried out for cervical flexion, extension, lateral flexion and cervical rotation. Adherence will be self-reported using an exercise diary²² for the conventional group. In contrast, it will be verified by the researchers as each session will be recorded and stored on the cloud for the telerehabilitation group.

Inclusion and exclusion criteria

Recruited participants will be included in this study based on the criteria : (1) residents of United Arab Emirates, both males and females(2) aged between 18 and 45 years (3) have normal body mass index, (4) referred to physiotherapy for chronic non-specific neck pain, (5) minimum pain score of 3 cm on the VAS, (6) pain onset at least 3weeks ago and (7) have given informed consent for voluntary participation. The exclusion criteria will be as follows (1): diagnosed by a physician with any pathological condition as cause of chronic neck pain, (2) presently undergoing any physical treatment or taking any medication for said pain, (3) has comorbidities, such as diabetes and hypertension, (4) has conditions such as migraine and cervicogenic headache, (5) has vertigo and/or vertebrobasilar insufficiency, (6) physically disabled or has recent immobilising injury, (6) orthopaedic conditions, such as spondylosis, spondylolisthesis, wryneck and (8) history of neurological conditions.

Recruitment, screening and informed consent

To advertise the study's participant recruitment, e-posters containing study details will be distributed around the 9

University of Sharjah. Those who express interest in participating can receive an information sheet via a QR code or by contacting the researchers. Participation is completely voluntary. The researcher will assess the individual's eligibility for the study, and only once all the criteria are satisfied will they be asked to sign a digital informed consent form that will be generated using Microsoft Forms.

Randomisation, allocation and blinding

Using the permuted block randomisation method, the researcher will randomise the study participants into two groups: the telerehabilitation group and the conventional group. Five permuted blocks will be used, each with a size of 6, for example, ABABAB, BABABA, AAABBB, AABBAB and BBAABA. Allocation will be done by the study's coinvestigator using sequentially numbered, sealed, opaque envelopes as a concealment method. Due to the nature of the study, blinding of researchers or participants will not be possible.

Exercise programme

All participants will have an in-person session with the physiotherapist so that all exercises can be demonstrated to them before beginning the programme. They will conduct the exercises independently at home for 6weeks, thrice a week, giving 18 sessions, each lasting 30 min. The software group will do each session via the CareSpace software that will record and store the entirety of the session on the cloud, giving the therapist access to review it. On the other hand, the conventional group would be given a flyer with written instructions on how to perform each exercise. After 2 weeks, the physiotherapist will hold the first review session with each participant, held online face to face for those in the software group (via the ConnectToMyDoctor application) and over the telephone for those in the conventional group. Similarly, after fourweeks, the second review session will be held. Progressions for exercises will be given to the participants at both review sessions. After completing all 6 weeks of the exercise programme, post-test measurements will be carried out in person. The exercise programme will be as follows (figure 1):

Strengthening exercises: chin tucks—5 reps progressing to 10 reps, chin tucks with overpressure—5 reps progressing to 10 reps,⁸ shoulder blade pulls—5 reps progressing to 10 reps, shoulder shrugs—10 reps progressing to 2 sets, shoulder rotations—20 reps clockwise and 20 reps anticlockwise.²³ Stretching exercises: forward and backward bend, side-bending, towel stretch—holding each position for 30 s, 3–5 reps.⁷¹⁴

Measures

Primary outcome measure Adherence

Adherence indicates how well a patient complies with given professional advice regarding a home exercise programme (frequency per week and duration per session).²⁴ This study will be self-reported using an exercise diary.²² For the telerehabilitation group, it will be verified by the researchers as each session will be recorded and stored on the cloud.

Secondary outcome measures

Pain

Pain intensity is self-reported on the VAS Pain, which is a continuous scale in the form of a 100 mm line, marked by 'no pain' (score of 0) on one end and 'pain as bad as it could be'(score of 100) on the other end. The participant must make a perpendicular line on the VAS scale that best represents their pain intensity. The reliability of this scale is good (0.94), in addition to the validity for chronic conditions ranges from 0.62 to 0.91, making it

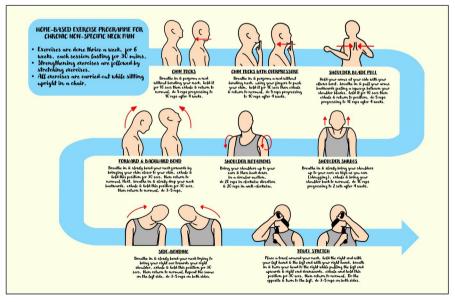


Figure 1 Home-based exercise programme for chronic non-specific neck pain.

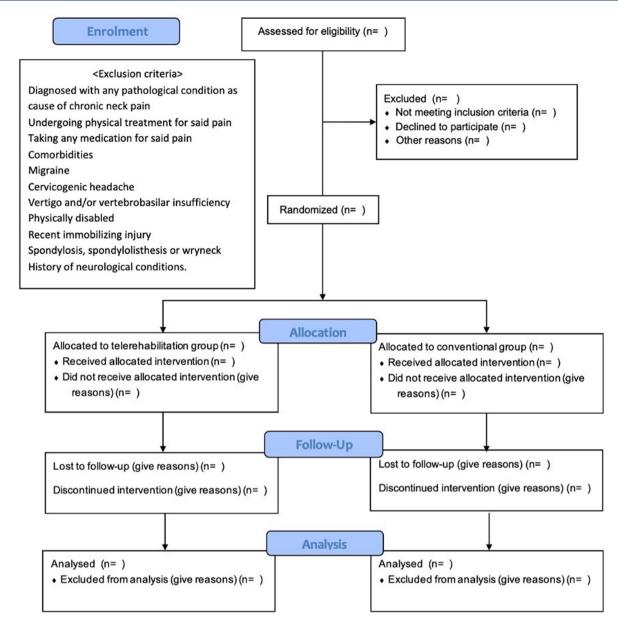


Figure 2 CONSORT (Consolidated Standards of Reporting Trails) flow diagram depicting the progress through the steps of a parallel two-group RCT.

ideal for use in this study.^{19 25} This will be considered the primary outcome.

Disability

The NDI is a standard self-reporting questionnaire to measure neck pain and disability due to said neck pain. It consists of 10 items, each scored from 0 to 5, giving a total of 50, where a higher score indicates increased disability.²⁶ The alpha coefficient is 0.08, implying good reliability for measuring neck pain and disability.²⁰

Cervical ROM

The CROM will be assessed using the CROM instrument to measure the ROM for cervical flexion and extension, lateral bending and rotation to both sides.²⁷ The CROM instrument is used as it holds compasses in each plane,

Endurance

The participant will be supine and head neutral for the CCFT. A pressure biofeedback unit will be placed under the cervical region, starting pressure at 20 mmHg. The participant will be required to perform a gentle head-nodding movement (chin tuck), attempting to hold the position for 10s at five gradually increasing pressure levels, from 22 mm Hg to 30 mm Hg.^{21 29} The highest pressure level maintained will be noted. The intraclass correlation coefficient for intraexaminer and interexaminer reliability is moderate (0.63-0.86).³⁰

mounted in a firm headgear, thereby showing good

validity and reliability for CROM measurement.²⁸

Pretest and post-test assessments will be conducted in a private room at the University of Sharjah. All data will be stored on a secure account in a secure computer. For those in the telerehabilitation group, recorded videos will be stored in the cloud, and only the primary investigator (female) will have access to this. The software provider company or anyone else in the university department cannot access this data. All patient information and data will be kept confidential. The participant's name will not be used for any publication or presentation.

Statistical analysis

Sample size

A total sample size of 30 participants in each group (figure 2), both male and female, will be satisfactory as calculated based on the effect size of 0.95 using mean and SD values of VAS, with alpha error of 5%, power of the study 80% and allocation ratio of $1.^{15}$ In case participants drop out of the study, intention-to-treat analysis will be carried out for all participants included in the study.

Data analysis

On completion of all exercise sessions, pain score, disability index, CROM and cervical muscle endurance outcome measures from all participants will be repeated, in addition to adherence. The distribution of the data will be analysed using Shapiro-Wilk test. Descriptive analyses will calculate frequencies, means and SD. For baseline differences between groups, an independent samples t-test will be used. Repeated measures analysis of variance will be used for within-group and between-group analyses at three different time points (0 weeks, 3 weeks, 6 weeks). A p<0.05 will be considered significant. Statistical analyses will be done by using SPSS V.26.0.

Patient and public involvement

There was no patient or public involvement in the design of this study.

DISCUSSION

Chronic non-specific neck pain is a growing healthcare concern.³ This study protocol describes the methodology used to evaluate how effective telerehabilitation is as an exercise programme delivery mode in patients with chronic non-specific neck pain compared with paper-based instructions. Using a randomised controlled design, this study aims to establish the effectiveness of telerehabilitation exercise intervention by measuring the pain score, disability index, CROM, cervical muscle endurance and, most importantly, adherence to the exercise programme. While home-based exercise programmes have proven to reduce neck pain and disability as well as improve functionality in patients, an issue many studies observed was the low adherence of these patients to the prescribed exercises.¹⁰¹⁷ Consequently, telerehabilitation is deemed an appropriate exercise

programme delivery mode to ensure patients consistently follow the prescribed frequency and time of exercise sessions.¹⁴ Telerehabilitation might just solve the lack of patient adherence to prescribed exercise programmes. Based on the results of this study, healthcare providers would be urged to adopt this mode of intervention, a possible extension to in-patient care, for its convenience, cost-effectiveness and, mainly, patient adherence. Telerehabilitation can ensure the success of subsequent exercise sessions and, thereby, treatment programmes for patients with chronic nonspecific neck pain.^{13 15}

Dissemination

The results of this study will be disseminated via publication in conference presentations, disciplinary-specific journals and as part of a master's thesis.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by University of Sharjah Research Ethics Committee (REC-23-02-27-01-PG). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Datasets are available on reasonable request to the corresponding author.

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REFERENCES

- 1 de Zoete RM, McAuley JH, Armfield NR, et al. The comparative effectiveness of physical exercise interventions in individuals with chronic non-specific neck pain: protocol for a network metaanalysis. BMJ Open 2020;10:e034846.
- 2 Goode AP, Freburger J, Carey T. Prevalence, practice patterns, and evidence for chronic neck pain. *Arthritis Care Res (Hoboken)* 2010;62:1594–601.
- 3 O'Riordan C, Clifford A, Van De Ven P, et al. Chronic neck pain and exercise interventions: frequency, intensity, time, and type principle. Arch Phys Med Rehabil 2014;95:770–83.
- 4 Kääriä Ś, Laaksonen M, Rahkonen O, et al. Risk factors of chronic neck pain: A prospective study among middle-aged employees. Eur J Pain 2012;16:911–20.
- 5 Bertozzi L, Gardenghi I, Turoni F, et al. Effect of therapeutic exercise on pain and disability in the management of chronic nonspecific neck pain: systematic review and meta-analysis of randomized trials. *Phys Ther* 2013;93:1026–36.

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- 6 Khan M, Soomro RR, Ali SS. The effectiveness of Isometric exercises as compared to general exercises in the management of chronic non-specific neck pain. *Pak J Pharm Sci* 2014;27(5 Suppl):1719–22.
- 7 Kim JY, Kwag KI. Clinical effects of deep Cervical Flexor muscle activation in patients with chronic neck pain. J Phys Ther Sci 2016;28:269–73.
- 8 Borisut S, Vongsirinavarat M, Vachalathiti R, *et al.* Effects of strength and endurance training of superficial and deep neck muscles on muscle activities and pain levels of females with chronic neck pain. *J Phys Ther Sci* 2013;25:1157–62.
- 9 Painkra J, Kumar S, Anwer S, et al. 2014_Painkra J_Reliability of an assessment of deep neck Flexor muscle endurance test. International Journal of Therapy and Rehabilitation 2014;21:227–31.
- 10 Gross A, Forget M, St George K, et al. Patient education for neck pain. Cochrane Database Syst Rev 2012.
- 11 Cottrell MA, O'Leary SP, Raymer M, et al. Does Telerehabilitation result in inferior clinical outcomes compared with in-person care for the management of chronic musculoskeletal spinal conditions in the tertiary hospital setting? A non-randomised pilot clinical trial. J Telemed Telecare 2021;27:444–52.
- 12 Jay K, Schraefel MC, Brandt M, et al. Effect of Video-based versus personalized instruction on errors during elastic tubing exercises for musculoskeletal pain: A randomized controlled trial. *Biomed Res Int* 2014;2014.
- 13 Bennell KL, Marshall CJ, Dobson F, et al. Does a web-based exercise programming system improve home exercise adherence for people with musculoskeletal conditions?: A randomized controlled trial. Am J Phys Med Rehabil 2019;98:850–8.
- 14 Gialanella B, Ettori T, Faustini S, et al. Home-based Telemedicine in patients with chronic neck pain. Am J Phys Med Rehabil 2017;96:327–32.
- 15 Ozer AY, Kapsigay B, Şenocak E, et al. Effectiveness of different exercise programs in individuals with non-specific neck pain: Telerehabilitation, given with synchronous exercises versus Homebased exercise. Med Sport J Rom Sport Med Soc [Internet] 2021;17:3327–35. Available: https://www.proquest.com/scholarlyjournals/effectiveness-different-exercise-programs/docview/ 2615893318/se-2?accountid=48149
- 16 Price J, Rushton A, Tyros I, *et al.* Effectiveness and optimal dosage of exercise training for chronic non-specific neck pain: A systematic review with A narrative synthesis [Internet]. *PLoS ONE* 2020;15:e0234511.
- 17 Wahezi SE, Duarte RA, Yerra S, et al. Telemedicine during COVID-19 and beyond: A practical guide and best practices Multidisciplinary

approach for the orthopedic and neurologic pain physical examination. *Pain Physician* 2020;23:S205–38.

- 18 Fandim JV, Costa LO, Yamato TP, et al. Telerehabilitation for neck pain. Cochrane Database Syst Rev 2021;2021.
- 19 Hawker GA, Mian S, Kendzerska T, et al. Measures of adult pain: visual analog scale for pain (VAS pain). Arthritis Care Res 2011;63:240–52.
- 20 Vernon H, Mior S. The neck disability index: a study of Reliability and validity. In: *Journal of Manipulative and Physiological Therapeutics* Bayview Avenue, Toronto, ON, Canada: Mosby Publishing Company, 1900: 14. 409–15.
- 21 De Araujo FX, Ferreira GE, Scholl Schell M, et al. Measurement properties of the Craniocervical flexion test: A systematic review. *Phys Ther* 2020;100:1094–117.
- 22 Nicolson PJA, Hinman RS, Wrigley TV, et al. Self-reported home exercise adherence: A validity and reliability study using concealed accelerometers. J Orthop Sports Phys Ther 2018;48:943–50.
- 23 Salo P, Ylönen-Käyrä N, Häkkinen A, et al. Effects of long-term home-based exercise on health-related quality of life in patients with chronic neck pain: A randomized study with a 1-year follow-up. *Disabil Rehabil* 2012;34:1971–7.
- 24 Medina-Mirapeix F, Éscolar-Reina P, Gascón-Cánovas JJ, *et al.* Predictive factors of adherence to frequency and duration components in home exercise programs for neck and low back pain: an observational study. *BMC Musculoskelet Disord* 2009;10:1–9.
- 25 Lemeunier N, da Silva-Oolup S, Olesen K, *et al.* Reliability and validity of self-reported questionnaires to measure pain and disability in adults with neck pain and its associated disorders: part 3—a systematic review from the CADRE collaboration. *Eur Spine J* 2019;28:1156–79.
- 26 En MCC, Clair DA, Edmondston SJ. Validity of the neck disability index and neck pain and disability scale for measuring disability associated with chronic, non-traumatic neck pain. *Man Ther* 2009;14:433–8.
- 27 Sukari AAA, Singh S, Bohari MH, et al. Examining the range of motion of the Cervical spine: Utilising different bedside instruments. *Malays J Med Sci* 2021;28:100–5.
- 28 Yee Won YK. The Reliability and validity on measuring tool of Cervical range of motion: A review. SMIC 2019;1:1–4.
- 29 Chiu T, Law EYH, Chiu T, et al. Performance of the Craniocervical flexion. J Orthop Sport Phys Ther 2005;35:567–71.
- 30 Jørgensen R, Ris I, Falla D, et al. Reliability, construct and Discriminative validity of clinical testing in subjects with and without chronic neck pain. *BMC Musculoskelet Disord* 2014;15.